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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,429	03/14/2006	Alessio Moriconi	3765-0116PUS1	6234
2292 7590 03/13/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER NOLAN, JASON MICHAEL	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 03/13/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/541,429	Applicant(s) MORICONI ET AL.	
	Examiner JASON NOLAN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 12 is/are rejected.
- 7) ☒ Claim(s) 9-11 and 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/05/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment – After Non-Final Rejection, filed 12/05/2008. As filed, Claims 1, 3-12, & 15-17 are pending in the instant application; of which, Claims 1, 3-12, & 15 are currently amended and Claims 16 & 17 are new. Examiner points out that Applicant accidentally recites Application No.: 10/541,419 in the heading of the response, and the application No. is 10/541,429.

Response to Amendments/Arguments

Applicant's amendments with respect to Claims 1, 3-12, & 15 have been fully considered and are entered. The objections to Claims 7, 8, & 10 have been withdrawn per amendment. The 101/112 rejections of Claims 1-7 & 15 are withdrawn per amendment. The 112-indefinite rejections of Claims 1, 7, 8, 14, & 15 are withdrawn per amendment. The 112-enablement rejection of Claims 13-15 is withdrawn per amendment. Applicants traverse the 112-written description rejection of Claims 1-9 & 11-15, stating that the specification and the knowledge in the art (as evidenced by the enclosed references) provided sufficient support for one of skill in the art to understand that Applicants had possession of the claimed invention at the time of filing. Examiner agrees in part with respect to the specific A groups evidenced by the references and the specification; however, disagrees in part with respect to the plethora of different heteroaryls encompassed within the scope of A as previously presented. As currently amended, the rejection is moot because there is adequate support for the specific A groups instantly claimed; thus, the rejection is withdrawn per amendment.

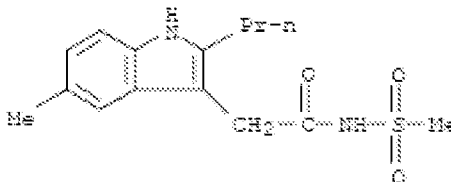
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,833,608. The patent discloses a compound that anticipates formula (I) wherein A = indole; X = C; Rd = Me; Hy = *n*Pr; & R = Me, (see ex. 35 in col. 12, ex. 84 in col. 17; and structure shown below).



Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 & 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in Claim 1, the term "diseases that involve IL-8 induced human PMN chemotaxis" is a relative term which renders the claims indefinite. The term "involve" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant

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application, does “involve” mean that the diseases are treated as a *direct* result of the compounds of formula (I) *inhibiting* or *activating* the PMN chemotaxis? Does it mean that the diseases are treated as an *indirect* result of the compounds of formula (I) *inhibiting* or *activating* the PMN chemotaxis? The term is ambiguous and multiple interpretations result. It is suggested that the specific diseases, i.e. those in Claim 15, be incorporated into Claim 1 such that the term "diseases that involve IL-8 induced human PMN chemotaxis" is made clear from the context.

Claim Objections

Claims 1 (Hy, Y twice), 8 (Rd), & 11 (Rd) are objected to because of the following informalities: said claims recite, in the indicated definitions, the term “C1-C6-cycloalkyl” and a ring must have at least three members. Appropriate correction is required.

Claims 9-11 & 15-17 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed

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within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is Jason.Nolan@uspto.gov. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The USPTO fax number for applications is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (either Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626